

K060006

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JAN 31 2006

510(k) Summary

Summary of Safety and Effectiveness

Company information

Braun GmbH
Frankfurter Strasse 145
61476 Kronberg
Germany

Device Identification

Trade Name – Braun ThermoScan® IRT 2000, infrared ear thermometer
Classification Name – Thermometer, Clinical, Electronic
Classification – Class II
Product Code – FLL

Predicate Device

Braun ThermoScan® IRT 4000 Series infrared ear thermometer

Device Description

Braun ThermoScan infrared ear thermometers are hand-held, battery-powered devices that are intended to be used for the intermittent measurement and monitoring of human body temperature of people of all ages. They measure infrared energy that is emitted from the tympanic membrane and surrounding tissue.

Intended Use and Indications for Use

Intermittent measurement and monitoring of human body temperature on people of all ages by consumers in a home use environment.

Comparison of the Braun ThermoScan IRT 2000 with the Braun ThermoScan IRT 4000 Series infrared ear thermometer

The basic design and fundamental technology of the Braun ThermoScan IRT 2000 and the Braun ThermoScan IRT 4000 Series infrared ear thermometers are similar. The operating range, temperature display, speculum, and the lens filters are the same. The materials used to fabricate the thermometer case, speculum, buttons, and lens filters are the same. The accuracy and reliability specifications are the same for the IRT 2000 and IRT 4000 series thermometers.

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The primary differences between the Braun ThermoScan IRT 2000, and the IRT 4000 series thermometers include a simpler mechanical design that allows for the industrial design to be modified so that the thermometer case is a smaller package. The LCD placement has been modified. The integrated heating element has been deleted from the ambient sensor at the probe tip that results in a faster temperature measuring cycle (i.e., IRT 2000 = ≤ 1 second, IRT 4000 = 3 to 10 seconds). The IRT 2000 has a single memory while the IRT 4000 has up to eight memories.

Compliance with Consensus Standards

The Braun Thermoscan IRT 2000 conforms to Consensus Standards. It conforms to the relevant portions of **ASTM E1965-98** – Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature. In addition, the Braun ThermoScan IRT 2000 conforms to the relevant portions of ISO and IEC consensus standards that FDA has adopted and that are applicable to infrared ear thermometers.

Compliance with Design Controls

Design Control activities for these devices have been performed in conformance with the design control procedure requirements as specified in 21 CFR Part 820.30. Risks associated with each product family have been identified and evaluated using Failure Modes and Effects Analysis (FMEA) and, after mitigation, the risks fall into the "Broadly Acceptable Region" following ISO 14971.

The modified device was subjected to the same series of laboratory tests to which the predicate device was subjected. The IRT 2000 will have passed each of the laboratory tests prior to commercial distribution of the device.

Design Validation – Clinical Results

Clinical comparison and repeatability testing was performed on the following four age groups; 0-3 years, 4-10 years, 11-65 years, and >65 years. The protocol that was used was essentially the same as the protocol used to demonstrate the clinical accuracy and repeatability of IRT 4000. This clinical comparison study demonstrated that the Braun ThermoScan IRT 2000 measures ear canal temperature as well as the previously 510(k) cleared IRT 4000 series thermometers in all age groups. The ear temperatures obtained with the IRT 2000 were highly related to temperatures measured at the oral and axillary sites. Differences were within clinical acceptability. The clinical repeatability of the device is statistically and clinically acceptable.

Substantial Equivalence and Conclusion

The Braun ThermoScan IRT 2000 infrared thermometer:

- conforms to Consensus Standards that are applicable to infrared ear thermometers,
- is technically and functionally substantially equivalent to the predicate device,
- has the same intended use and indications for use, and
- functions similarly in the hands of consumers.

Therefore, the Braun ThermoScan IRT 2000, infrared ear thermometer does not raise any significant new issues of safety or efficacy and, in the opinion of the submitter, is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2006

Braun GmbH
C/O Mr. Fred Schlador
President
Regulatory Resources, LLC
P.O. Box 1490
Eagle, Idaho 83616

Re: K060006
Trade/Device Name: Braun ThermoScan® IRT 2000 Infrared Ear Thermometer
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: December 30, 2005
Received: January 3, 2006

Dear Mr. Schlador:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

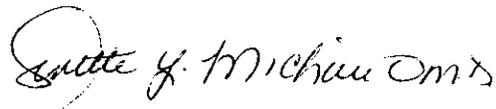
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K060006

Indications for Use

510(k) Number (if known):

Device Name:

Braun ThermoScan® IRT 2000 infrared ear thermometer

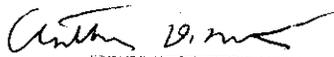
Indications for Use:

The Braun ThermoScan IRT 2000 infrared ear thermometer is indicated for the intermittent measurement and monitoring of human body temperature by consumers in a home use environment.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Director, Office of Device Evaluation, General Hospital,
Central Devices

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